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Pursuant to Federal Rule of Civil Procedure 26(f), on November 3, 2021, the following parties to this action met and conferred via telephone conference on the topics outlined in this report and discovery plan:

- Russell E. Blythe and Kathleen E. McCarthy, counsel for Plaintiff/Counterclaim Defendant Irrimax Corporation (“Irrimax”);
- Jason Carruthers, William E. Manske, George B. Ashenmacher counsel for Defendant/Counterclaimant Next Science, LLC (“Next Science”).

**1. Description of Case:**

(a) Describe briefly the nature of this action.

Irrimax filed this action alleging false advertising in violation of 15 U.S.C. § 1125(a) and common law unfair competition against Next Science based on advertising materials for Next Science’s XPERIENCE product. Next Science filed counterclaims alleging false advertising in violation of 15 U.S.C. § 1125(a) and common law unfair competition against Irrimax based on advertising materials for Irrimax’s Irrisept product. Each party denies liability regarding the other party’s respective claims.

(b) Summarize, in the space provided below, the facts of this case. The summary should not be argumentative nor recite evidence.

**Irrimax's Summary:**

Irrimax has developed and markets its Irrisept Antimicrobial Wound Lavage—a single-use, manual, self-contained irrigation device comprised of 0.05% Chlorhexidine Gluconate (CHG) in 99.95% water. Next Science offers a competing wound irrigation product under the name XPERIENCE. Next Science has made certain statements in its advertising materials for its XPERIENCE product that Irrimax contends constitute false advertising under Section 43(a) of the Lanham Act and under related state laws.

Examples of Next Science's false and misleading statements made in advertising and promotion for its XPERIENCE product include the following:

- a. Next Science makes false and/or misleading comparative statements referring to Irrimax's Irrisept product, falsely claiming that tests prove Next Science's XPERIENCE product outperforms Irrisept without reliable support for such claims;
- b. Next Science makes false and/or misleading statements touting that XPERIENCE is cleared by the FDA while asserting purported benefits based on chemical mechanisms of action that the FDA has not cleared for use; and
- c. Next Science makes false and/or misleading statements that XPERIENCE is a "no rinse" solution that works by remaining in the body, but

XPERIENCE is for external use only, must be suctioned out during use, and may also require a rinse.

These claims by Next Science relate to the inherent qualities of the Next Science and Irrimax products, are material to the purchasing decisions of those who buy and utilize the products at issue, have a tendency to deceive and/or have deceived the relevant purchasing public, and will cause or have caused harm to Irrimax.

In regard to Next Science's counterclaims, Irrimax states that it has not made any false or misleading claims in its marketing materials for Irrisept. Irrimax denies liability and further states that Next Science is not entitled to any of the relief it has requested.

**Next Science's Summary:**

Next Science developed and markets its EXPERIENCE™ No Rinse Antimicrobial Solution as an alternative to less effective wound irrigation products. Irrimax has made certain false and misleading statements regarding EXPERIENCE™ in its advertising and marketing materials, which constitute false advertising under Section 43(a) of the Lanham Act and Georgia common law.

For example, Irrimax has circulated inaccurate product comparisons purporting to demonstrate that EXPERIENCE™ is not sterilely packaged or filtered; does not have Kinetic Kill data; has not been subject to third party biofilm studies;

and/or needs an additional device to operate. Irrimax has further distributed false and misleading literature implying that XPERIENCE™ is dangerous, uncomfortable, and is not a no-rinse solution.

For its part, Irrimax asserts that aspects of Next Science's XPERIENCE™ product literature are false and misleading. Next Science denies these allegations. Laboratory testing and other product-specific materials verify the veracity of the subject statements identified by Irrimax.

- (c) The legal issues to be tried are as follows:
- (1) Whether Next Science violated section 43(a) of the Lanham Act.
  - (2) Whether Next Science is liable for common law unfair competition.
  - (3) Whether Irrisept has been injured by Next Science's advertising.
  - (4) Whether Irrisept violated section 43(a) of the Lanham Act.
  - (5) Whether Irrisept is liable for common law unfair competition.
  - (6) Whether Next Science has been injured by Irrisept's advertising.

This is an initial list of legal issues known to the parties at this time.

The parties reserve the right to raise additional legal issues that may have to be tried that become apparent through discovery.

(d) The cases listed below (include both style and action number) are:

(1) Pending Related Cases: none.

(2) Previously Adjudicated Related Cases: none.

2. This case is complex because it possesses one or more of the features listed below (please check):

- |              |   |
|--------------|---|
| _____        | (1) Unusually large number of parties                                 |
| _____        | (2) Unusually large number of claims or defenses                      |
| _____        | (3) Factual issues are exceptionally complex                          |
| _____        | (4) Greater than normal volume of evidence                            |
| <u>  X  </u> | (5) Extended discovery period is needed                               |
| _____        | (6) Problems locating or preserving evidence                          |
| _____        | (7) Pending parallel investigations or action by government           |
| <u>  X  </u> | (8) Multiple use of experts   |
| _____        | (9) Need for discovery outside United States boundaries               |
| _____        | (10) Existence of highly technical issues and proof                   |
| _____        | (11) Unusually complex discovery of electronically stored information |

**3. Counsel:**

The following individually-named attorneys are hereby designated as lead counsel for the parties:

Plaintiff/Counterclaim Defendant:	Russell E. Blythe, Kathleen E. McCarthy
Defendant/Counterclaimant:	Anne M. Lockner, William E. Manske

**4. Jurisdiction:**

Is there any question regarding this Court's jurisdiction?

\_\_\_\_\_ Yes            X   No

If "yes," please attach a statement, not to exceed one page, explaining the jurisdictional objection. When there are multiple claims, identify and discuss separately the claim(s) on which the objection is based. Each objection should be supported by authority.

**5. Parties to This Action:**

(a) The following persons are necessary parties who have not been joined:

None.

(b) The following persons are improperly joined as parties:

None.

(c) The names of the following parties are either inaccurately stated or necessary portions of their names are omitted:

None.

(d) The parties shall have a continuing duty to inform the Court of any contentions regarding unnamed parties necessary to this action or any contentions regarding misjoinder of parties or errors in the statement of a party's name.

**6. Amendments to the Pleadings:**

Amended and supplemental pleadings must be filed in accordance with the time limitations and other provisions of Fed. R. Civ. P. 15. Further instructions regarding amendments are contained in LR 15.

(a) List separately any amendments to the pleadings that the parties anticipate will be necessary:

None anticipated at this time. The parties reserve the right to revisit amendments to the pleadings after discovery.

**7. Filing Times For Motions:**

All motions should be filed as soon as possible. The local rules set specific filing limits for some motions. These times are restated below.

All other motions must be filed WITHIN THIRTY DAYS after the beginning of discovery, unless the filing party has obtained prior permission of the court to file later. Local Rule 7.1A(2).

(a) Motions to Compel: before the close of discovery or within the extension period allowed in some instances. Local Rule 37.1.

(b) Summary Judgment Motions: within thirty days after the close of discovery, unless otherwise permitted by court order. Local Rule 56.1.

(c) Other Limited Motions: Refer to Local Rules 7.2A; 7.2B, and 7.2E, respectively, regarding filing limitations for motions pending on removal, emergency motions, and motions for reconsideration.

(d) Motions Objecting to Expert Testimony: Daubert motions with regard to expert testimony no later than the date that the proposed pretrial order is submitted. Refer to Local Rule 7.2F.

The parties have proposed in Section 10, below, a detailed schedule that includes filing times for various motions, which the parties respectfully submit should control in this action.



**8. Initial Disclosures:**

The parties are required to serve initial disclosures in accordance with Fed.R.Civ.P. 26. If any party objects that initial disclosures are not appropriate, state the party and basis for the party's objection. NOTE: Your initial disclosures should include electronically stored information. Refer to Fed. R. Civ. P. 26(a)(1)(B).

The parties do not object to serving initial disclosures.

**9. Request for Scheduling Conference:**

Does any party request a scheduling conference with the Court? If so, please state the issues which could be addressed and the position of each party.

The parties do not currently request a scheduling conference with the Court, but stand ready to address any questions or concerns the Court may have about the parties proposed schedule herein.

**10. Discovery Period:**

The discovery period commences thirty days after the appearance of the first defendant by answer to the complaint. As stated in LR 26.2A, responses to initiated discovery must be completed before expiration of the assigned discovery period.

Cases in this Court are assigned to one of the following three discovery tracks: (a) zero month discovery period, (b) four months discovery period, and (c) eight months discovery period. A chart showing the assignment of cases to a discovery track by filing category is contained in Appendix F. The track to which a particular case is assigned is also stamped on the complaint and service copies of the complaint at the time of filing.

Please state below the subjects on which discovery may be needed:

Irrimax anticipates discovery on at least the following subjects: (1) Next Science and third party testing of the parties' wound irrigation products; (2) Next Science's advertising, marketing, and promotion of XPERIENCE; (3) comparisons of XPERIENCE with other products; (4) attempts to obtain FDA clearance for XPERIENCE; (5) complaints, warning letters, and other similar information related to XPERIENCE; (6) investigations, analyses, and reports regarding advertising, marketing, promotion, performance, and FDA clearance of XPERIENCE; (7) Next Science's internal and external communications regarding advertising, marketing, promotion, performance, and FDA clearance of XPERIENCE; (8) purchaser impressions related to the advertising, marketing, and promotion of XPERIENCE; (9) sales and distribution of XPERIENCE; (10) the scope of injunctive relief and corrective advertising; and (11) damages and the amount of monetary relief.

Next Science anticipates discovery on at least the following subjects: (1) Next Science, Irrimax, and third party testing of the parties' wound irrigation products, including testing and evaluation of Next Science's XPERIENCE<sup>TM</sup> product and Irrimax's Irrisept product; (2) the development and function of Next Science's XPERIENCE<sup>TM</sup> product and Irrimax's Irrisept product; (3) Irrimax's advertising, marketing, and promotion of Irrisept; (4) comparisons of Irrisept with other

products; (5) attempts to obtain FDA clearance for Irrisept; (6) complaints, warning letters, and other similar information related to Irrimax's Irrisept product; (7) investigations, analyses, and reports regarding advertising, marketing, promotion, performance, and FDA clearance of Irrisept; (8) Irrimax's internal and external communications regarding advertising, marketing, promotion, performance, and FDA clearance of Irrisept; (9) purchaser impressions related to the advertising, marketing, and promotion of Irrisept; (10) sales and distribution of Irrisept; (11) the scope of injunctive relief and corrective advertising; and (12) damages and the amount of monetary relief.

If the parties anticipate that additional time beyond that allowed by the assigned discovery track will be needed to complete discovery or that discovery should be conducted in phases or be limited to or focused upon particular issues, please state those reasons in detail below:

In light of the potential need for expert witness testimony and to promote an efficient discovery process, the parties respectfully request that discovery be conducted in accordance with the following deadlines:

<b>Date</b>	<b>Event</b>
November 17, 2021	Fact Discovery Opens
February 24, 2022	Substantial Completion of Document Discovery
April 28, 2022	Close of Fact Discovery

May 26, 2022	Expert Reports On Issues Where Party Bears Burden Of Proof Due
June 30, 2022	Rebuttal Expert Reports Due
July 28, 2022	Close of Expert Discovery

**11. Discovery Limitation and Discovery of Electronically Stored Information:**

(a) What changes should be made in the limitations on discovery imposed under the Federal Rules of Civil Procedure or Local Rules of this Court, and what other limitations should be imposed?

Unless altered by subsequent agreement of the parties or court order, the parties agree (1) not to require logging of privileged and work product communications after the filing date of this lawsuit; and (2) to serve discovery requests and responses and produce documents electronically.

Further, the parties agree that a stipulated confidentiality agreement and protective order should be entered in this case to protect documents exchanged in discovery that the producing party deems, in good faith, to be confidential. The parties will meet and confer on the proposed form of a confidentiality agreement and protective order and submit to the Court for approval.

(b) Is any party seeking discovery of electronically stored information?

  X   Yes

       No

If “yes,”

(1) The parties have discussed the sources and scope of the production of electronically stored information and have agreed to limit the scope of production (e.g., accessibility, search terms, date limitations, or key witnesses) as follows:

The parties are continuing to discuss the procedures for streamlining the production of electronically stored information and plan to submit a stipulation regarding the procedures governing that phase of discovery.

(2) The parties have discussed the format for the production of electronically stored information (e.g., Tagged Image File Format (TIFF or .TIF files), Portable Document Format (PDF), or native), method of production (e.g., paper or disk), and the inclusion or exclusion and use of metadata, and have agreed as follows:

The parties’ stipulation regarding electronic discovery will address the format of the production. In the absence of agreement on issues regarding discovery of electronically stored information, the parties shall request a scheduling conference in paragraph 9 hereof.

## **12. Other Orders:**

What other orders do the parties think that the Court should enter under Rule 26(c) or under Rule 16(b) and (c)?

As noted above, the parties will meet and confer on the proposed form of a stipulated confidentiality agreement and protective order and submit to the Court for approval.

**13. Settlement Potential:**

(a) Lead counsel for the parties certify by their signatures below that they conducted a Rule 26(f) conference that was held on November 3, 2021, and that they participated in settlement discussions. Other persons who participated in the settlement discussions are listed according to party.

For plaintiff: Lead counsel (signature): /s/Russell E. Blythe

Other participants: Kathleen E. McCarthy

For defendant: Lead counsel (signature): /s/William E. Manske

Other participants: George B. Ashenmacher, Jason Carruthers

(b) All parties were promptly informed of all offers of settlement and following discussion by all counsel, it appears that there is now:

- ☐ A possibility of settlement before discovery.
- ☒ A possibility of settlement after discovery.
- ☐ A possibility of settlement, but a conference with the judge is needed.
- ☐ No possibility of settlement.

(c) Counsel (☒) do or (☐) do not intend to hold additional settlement conferences among themselves prior to the close of discovery. The proposed date of the next settlement conference is to be determined.

(d) The following specific problems have created a hindrance to settlement of this case.

None.

**14. Trial by Magistrate Judge:**

Note: Trial before a Magistrate Judge will be by jury trial if a party is otherwise entitled to a jury trial.

(a) The parties (\_\_\_\_) do consent to having this case tried before a magistrate judge of this Court. A completed Consent to Jurisdiction by a United States Magistrate Judge form has been submitted to the clerk of court this \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_.

(b) The parties (  X  ) do not consent to having this case tried before a magistrate judge of this Court.

This 17th day of November, 2021.

/s/ William E. Manske  
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### **CERTIFICATE OF COMPLIANCE**

I hereby certify, in compliance with Local Rule 5.1C, that the foregoing pleading has been prepared using 14 point Times New Roman font, with a top margin of not less than 1.5 inches and a left margin of not less than 1 inch.

/s/ Russell E. Blythe  
Russell E. Blythe

**CERTIFICATE OF SERVICE**

I hereby certify that on this date, I electronically filed the foregoing JOINT PRELIMINARY REPORT AND DISCOVERY PLAN with the Clerk of Court using the CM/ECF system, which automatically sends e-mail notification of such filing to all attorneys of record.

This 17th day of November, 2021.

/s/ *Russell E. Blythe*  
Russell E. Blythe